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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,024	07/01/2002	Thorsten Lehmann-Lintz	5/1272US	5481
28505	7590	04/19/2004		
BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877				
			EXAMINER BERNHARDT, EMILY B	
			ART UNIT 1624	PAPER NUMBER

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,024

Applicant(s)

LEHMANN-LINTZ ET AL.

Examiner

Emily Bernhardt

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-17 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15 is/are allowed.
- 6) ☒ Claim(s) 11-14, 16, 17 and 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

In view of applicants' response filed 12/24/03 the following applies.

Upon review of the contents of the file which is now in electronic form the abstract was found and thus the objection removed.

Claims 11-14,16,17,19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. In amending a large portion of claim 11 the R12 definition requires clarification. Note on p.3 "C1-4 alkoxy group" appears to be extraneous. Should it be deleted ?
2. With most of the text deleted in claim 13 the sole line remaining on p.8 may not be seen by the printer should the case pass to issue. A clean claim (vs. just a marked-up one) is needed.
3. In claims 11 and 14 commas to be deleted show a line above the comma rather than through it. See second line of p.3 and p.8 3rd line of claim 14.
4. In process claim 21 for route b) after formula IV "wherein" now appears to be extraneous. Also, "or with the reactive derivatives thereof" appears out of place since it is referring to formula IV and not (V).

5. It is not clear why applicants deleted reference to claim 11 in defining the variables throughout this claim. Insertion of such would make it clear what the scope is for each and every reactant recited.

6. In method claim 19 what diseases or complications are covered by the term "the clinical sequela thereof". Specification gives no guidance and thus intended scope is not known.

In response to the above rejections applicants are requested to provide a clean set of claims (in addition to a marked-up copy) given the substantive deletions being made so that printing errors will be avoided should the case pass to issue.

Claim 20 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot refer back to 2 different sets of claims to different features. See MPEP § 608.01(n).

Claims 11-14,16,17,19-21 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Reason #2 of the previous action remains for the scope of Ra as heteroaryl. While applicants urge their

amendments overcome this rejection, it is not evident how given that the scope of "heteroaryl" is as broad as defined in the specification which is open-ended to the inclusion of other hetero atoms in 5-membered heteroaryls. Note the 2 rings only made as pointed out in the previous action. Applicants provide no sound reasoning why one skilled in the art would expect such diverse rings as pyridazines, triazines, oxazoles, tetrazoles, imidazoles, pyrazoles, as embraced herein at Ra to behave similarly to compounds made and tested. Evidence of art-recognized biological equivalency is not seen.

The obviousness double patenting rejection is withdrawn in view of the requirement that the het rings at Ra be monocyclic vs. polycyclics being claimed in copending 10/168486.

Claim 15 is allowed.

The claims' scope as now amended no longer overlaps with the acylated derivatives disclosed by Ohkura (WO'556). An EP equivalent which is in English is provided herewith.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is (571) 272-0664.

If attempts to reach the examiner by phone are unsuccessful, the supervisor for AU 1624, Dr. Mukund Shah, can be reached at (571)272-0674.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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A handwritten signature in cursive script, appearing to read "E Bernhardt".

EMILY BERNHARDT

PRIMARY EXAMINER

Group 1600